

REMARKS

Claims 6-10, 14, 18-24 and 28 were pending and stand rejected. Applicant has now canceled claims 18-24 without prejudice or disclaimer to the subject matter claimed therein.

Reconsideration is respectfully requested in view of the following remarks.

Before addressing the merits of the rejections, a brief review may be useful. The claimed invention is a new way of making porous polymers. In the prior art techniques, a polymer is dissolved in a solvent that is also miscible in a non-solvent. When the polymer solution is contacted to the non-solvent, the solution phase separates, often in the form of solid polymer precipitating out of solution; or otherwise sinking from a liquid phase, which will remain above said precipitate. By contrast, in the practice of the claimed invention, a polymer solution is gelled as a single phase, and solvent is extracted from the gel, leaving behind pores. That is, the polymer solution is contacted to a liquid substance referred to as a "second solvent", which does not cause a phase separation or a precipitation event, but instead causes the entire volume of solution to increase in viscosity, eventually reaching the consistency of a gel that can be shape-formed. The liquid substance is called a "second solvent" even though it does not dissolve the polymer. Rather, it swells solid polymer, and it gels a solution of the polymer.

Claims 8, 10, 23 and 24 were rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 5,077,049 to Dunn (hereinafter referred to as "Dunn"). Applicant respectfully traverses this rejection.

Dunn discloses a technique for assisting in the restoration of periodontal tissue. The technique involves placement of an in-situ forming biodegradable polymeric barrier adjacent the surface of the tooth. The barrier is microporous, and can include a biologically active agent. The barrier is made by dissolving the biodegradable polymer in a nontoxic and water-miscible solvent, and injecting the solution into a periodontal pocket. The solvent then diffuses or permeates out of the solution into body tissue, and the polymer coagulates. The system is made porous (or perhaps more porous) by incorporating water-soluble materials such as sugar or salt particles into the polymer solution. The paragraph in Dunn at column 6, lines 3-11 is indicative of his process:

For polymers that tend to *coagulate* slowly, a solvent mixture can be used to increase the *coagulation* rate. Thus, one liquid component of the mixture is a good solvent for the polymer, and the other component is a poorer solvent or a non-solvent. The two liquids are mixed at a ratio such that the polymer is still soluble but *precipitates* with the slightest physiological environment.

Both 'precipitate' and 'coagulate', as used above by Dunn, refer to the same phenomena of phase separation, and are therefore synonymous. Thus, it is clear that Dunn does not anticipate the claimed invention, because the claimed invention is not a precipitation phenomenon. The gelling in the claimed invention is of the **entire volume** of solution, and there is no visible phase separation. There is no precipitation.

Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Claims 6, 7, 9, 11, 18-23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Einstman in view of U.S. Patent No. 5,447,724 to Helmus and U.S. Patent No. 4,769,286 to LeNoane. Applicant respectfully traverses this rejection.

Einstman discloses a technique for making a microporous sheet, which involves rapidly coagulating a polymer solution to form a polymer gel. The polymer is dissolved in a solvent that is capable of being readily mixed with a non-solvent. Then, a small quantity of the non-solvent is added to the polymer solution, but not enough non-solvent is added to trigger coagulation. More exactly, the quantity is about 70-98% of the amount that would cause coagulation at that temperature. Then, the solution is quenched by at least 10C, preferably by cooling by about 15-30C in a non-solvent quenching medium. The chilled solution cannot hold the polymer in solution at the lower temperature, and thus the non-solvent causes coagulation as the polymer "crashes out" of solution. In a preferred embodiment, the quenching medium is the same non-solvent as is added to the solution in small quantities. By the term "gel" Einstman means that the polymer component partially separates from the solvent and non-solvent of the composition (col. 2, lines 11-14).

Applicant respectfully submits that Einstman neither discloses nor suggests the claimed invention which features in important part "gelling the entire volume of solution". Since Einstman has some degree of phase separation, something less than the entire volume of solution is gelled.

Neither Helmus nor LeNoane remedies this deficiency. Helmus discloses medical devices where a surface features a porous polymeric composition holding a biologically active compound. LeNoane discloses reinforcing materials such as fibers and rings. Further, the reinforcements of LeNoane are not stated as reinforcing porous polymers, and still further are intended for use in reinforced concretes, reinforced plastics and in the manufacture of optical-fiber cables. LeNoane is silent about reinforcing medical prostheses.

Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Claims 14 and 28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Dunn in view of Reischl. Applicant respectfully traverses this rejection.

Reischl discloses a technique for making a vapor permeable, microporous, leatherlike sheet material. The Reischl technique that is very similar to that of Einstman. A polymer solution is prepared. Then, at least 60% of the quantity of non-solvent that would cause precipitation of the solution, is added to the solution. The solution is then shaped, for example, by coating onto a substrate, and finally the solvent and non-solvent are evaporated, which solidifies the polymer. In col. 3, lines 21-27, Reischl elaborates on what the gelation phenomenon entails:

The quantity of non-solvent required to gell the solution can be determined by adding non-solvent dropwise to the solution with stirring until there is marked increase in viscosity and the mixture, after standing for a short while, for example, 1 to 5 minutes, forms a serum above or below a gelled, opaque, viscous and gel-like mass.

Thus, it is clear that Reischl's gelation takes place in connection with a phase separation. The claimed invention is clearly different from a combination of Dunn and Reischl. In the claimed invention, the entire volume of solution begins to gel as the swelling solvent is added. It does not exhibit phase separation as in the Reischl process. There is nothing in Dunn to suggest that Dunn can remedy this deficiency in Reischl, since it is clear that Dunn's "coagulation" is also a phase separation event.

In fact, each of Dunn, Einstman and Reischl seem to disclose the same basic technique and phenomenon: a small quantity of non-solvent is added to a polymer solution to bring the solution close to the "edge" of solubility, and then the physiological environment is changed (such as by quenching or by removing solvent), which pushes the solution over the edge and causes solid polymer to precipitate out of solution; thereby leaving a non-liquid precipitate distinct from the liquid phase.

Accordingly, Applicant respectfully requests that this rejection be withdrawn.

CONCLUSION

The claimed invention is neither disclosed nor suggested by any of Dunn, Einstman or Reischl, each of whom disclose coagulation of polymer solutions that involve precipitation or other some kind of phase separation event. The other applied references, Helmus and LeNoane, fail to

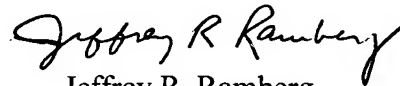
remedy this deficiency. In contrast, the claimed invention features the *entire* solution thickening to a gelation condition.

As a point of information, Dunn indeed discloses THF as a solvent for dissolving the polymer. See, for example, his column 5, line 46.

In view of the amendments and the above remarks, Applicant respectfully submits that the present application is in condition for allowance. Accordingly, Applicant respectfully requests issuance of a Notice of Allowance directed to claims 6-10, 14, and 28.

Should the Examiner deem that any further action on the part of Applicant would be desirable, the Examiner is invited to telephone Applicant's undersigned representative.

Respectfully submitted,



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